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EXAMINER

AGWUMEZIE, CHARLES C

ART UNIT

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3621

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/734,655	<b>Applicant(s)</b> BEHRENBRUCH ET AL.	
	<b>Examiner</b> CHARLES C. AGWUMEZIE	<b>Art Unit</b> 3621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 November 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 22-29, 31-35, 37, 38 and 40-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22-27, 29, 30 and 45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) 40, 31-35, 42-44 and 46 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>03/30/04</u> .  | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Acknowledgments***

1. Applicant amendment filed on November 19, 2007 is acknowledged.  
Accordingly claims 22-29, 31-35, 38, and 40-46 remain pending.

### ***Election/Restrictions***

2. Newly submitted claims 40, 31-35, 42-44 and 46 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claim 40 requires an adjusting functionality for modifying the plurality of adjustable functionalities in response to detection or failure to detect the distinctive signature characteristics of the processing agent. which was not required by the original presentation of claims.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 40, 31-35, 42-44 and 46 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. **Claim 37-38 and 41** is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Specifically claims 37-38 and 41 provide software instruction without further process of execution. They only constitute software in a computer readable medium. Therefore the claimed invention is directed to non-statutory subject matter.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 22-23, 29, and 39** are rejected under 35 U.S.C. 103(a) as being unpatentable over Arditi U.S. Patent No. 5,526,816 in view of Benaron U.S. Patent No. 5,167,297.

As per **claim 22**, Arditi et al discloses a processing method comprising the steps of:

administering a processing agent substance to a subject chosen from a human being, a plant and an animal, the processing agent having a primary behavior effective in combination with a processing system to achieve a desired process result, the processing agent further having a distinctive signature characteristic distinguishing it

from other processing agents (col. 1, lines 35-45, which discloses administrable ultrasound contrast agents; col. 6, lines 1-15, which discloses frequency -dependent behaviors of ultrasound contrast agents ... physical characteristics or signatures of contrast agent responses...);

testing for the distinctive signature characteristic of the processing agent using a test functionality of the processing system (col. 6, lines 1-15, which discloses contrast agent signatures is found to be the closest analogy to experimental observations);

selectively modifying subsequent operation of the processing system based on a result from the test for the distinctive signature characteristic of the processing agent (col. 3, lines 40-65, which discloses selecting at least two frequencies chosen to enhance the difference between contrast agent responses and tissue responses; col. 6, lines 5-20, which discloses that it can operate either in linear or non-linear response conditions).

What Arditi does not explicitly disclose is the processing agent further having a distinctive signature characteristic distinguishing it from other processing agents.

Benaron discloses the processing agent further having a distinctive signature characteristic distinguishing it from other processing agents (col. 7, lines 5-15, which discloses that multiple contrast agents, each of distinguishable optical signature...)

Accordingly it would have been obvious to one of ordinary skill in the art at time of applicant's invention to modify the method of Arditi and incorporate the method wherein the processing agent further having a distinctive signature characteristic

Art Unit: 3621

distinguishing it from other processing agents in view of the teachings of Benaron in order to ensure that the right agent is employed with the processing system.

As per **claim 24**, Arditi further discloses a method, wherein the administering step comprises administering a processing agent substance to a subject chosen from a human being, a plant and an animal, the processing agent having a first component for providing a primary behavior effective in combination with a processing system to achieve a desired process result and a second component having a distinctive signature characteristic distinguishing the processing agent from other processing agents (col. 1, lines 35-45, which discloses administrable ultrasound contrast agents; col. 6, lines 1-15, which discloses frequency -dependent behaviors of ultrasound contrast agents ... physical characteristics or signatures of contrast agent responses...).

What Arditi does not explicitly disclose is a second component having a distinctive signature characteristic distinguishing the processing agent from other processing agents.

Benaron discloses a second component having a distinctive signature characteristic distinguishing the processing agent from other processing agents (col. 7, lines 5-15, which discloses that multiple contrast agents, each of distinguishable optical signature...)

Accordingly it would have been obvious to one of ordinary skill in the art at time of applicant's invention to modify the method of Arditi and incorporate the method wherein a second component having a distinctive signature characteristic distinguishing

the processing agent from other processing agents in view of the teachings of Benaron in order to ensure that the right agent is employed with the processing system.

As per **claim 25**, Arditi further discloses a method, wherein the administering step comprises administering a processing agent substance to a human being, the processing agent having a primary behavior effective in combination with a processing system to achieve a desired process result, wherein the processing agent exhibits a distinctive signature characteristic after administration to the human being distinguishing the processing agent from other processing agents (col. 2, lines 5-20).

What Arditi does not explicitly disclose is wherein the processing agent exhibits a distinctive signature characteristic after administration to the human being distinguishing the processing agent from other processing agents.

Benaron discloses wherein the processing agent exhibits a distinctive signature characteristic after administration to the human being distinguishing the processing agent from other processing agents (col. 7, lines 5-15, which discloses that multiple contrast agents, each of distinguishable optical signature...)

Accordingly it would have been obvious to one of ordinary skill in the art at time of applicant's invention to modify the method of Arditi and incorporate the method wherein the processing agent exhibits a distinctive signature characteristic after administration to the human being distinguishing the processing agent from other processing agents in view of the teachings of Benaron in order to ensure that the right agent is employed with the processing system.

As per **claim 26**, Arditi further discloses a method, wherein the administering step comprises administering a processing agent substance to a human being, the processing agent having a primary behavior effective in combination with a processing system to achieve a desired process result, wherein the processing agent exhibits distinctive signature characteristic is in a time-dependent behavior of the processing agent in the human being, distinguishing the processing agent from other processing agents (see fig. 1, which discloses time circuits, time gain control; col. 2, lines 5-35).

What Arditi does not explicitly disclose is distinguishing the processing agent from other processing agents.

Benaron discloses distinguishing the processing agent from other processing agents (col. 7, lines 5-15, which discloses that multiple contrast agents, each of distinguishable optical signature...)

Accordingly it would have been obvious to one of ordinary skill in the art at time of applicant's invention to modify the method of Arditi and incorporate the method wherein distinguishing the processing agent from other processing agents in view of the teachings of Benaron in order to ensure that the right agent is employed with the processing system.

As per **claim 27**, Arditi further discloses a method wherein the administering step comprises administering a processing agent substance to a human being, the processing agent having a primary behavior effective in combination with a processing



system to achieve a desired process result, wherein the processing agent exhibits distinctive signature characteristic is in a spatially-dependent behavior of the processing agent after administration to the human being, distinguishing the processing agent from other processing agents (col. 5, lines 40-50; col. 6, lines 5-20, which discloses “frequency-dependency”).

What Arditi does not explicitly disclose is distinguishing the processing agent from other processing agents.

Benaron discloses distinguishing the processing agent from other processing agents (col. 7, lines 5-15, which discloses that multiple contrast agents, each of distinguishable optical signature...)

Accordingly it would have been obvious to one of ordinary skill in the art at time of applicant’s invention to modify the method of Arditi and incorporate the method wherein distinguishing the processing agent from other processing agents in view of the teachings of Benaron in order to ensure that the right agent is employed with the processing system.

As per **claim 28**, Arditi further discloses a method wherein the administering step comprises administering a processing agent substance to a subject chosen from a human being, a plant and an animal, the processing agent having a primary behavior effective in combination with a processing system to achieve a desired process result and a property detectable by the processing system distinguishing the processing agent

from other processing agents (col. 3, lines 40-65, which discloses detection of ultrasound backscatter of a region containing a contrast agent...).

What Arditi does not explicitly disclose is distinguishing the processing agent from other processing agents.

Benaron discloses distinguishing the processing agent from other processing agents (col. 7, lines 5-15, which discloses that multiple contrast agents, each of distinguishable optical signature...)

Accordingly it would have been obvious to one of ordinary skill in the art at time of applicant's invention to modify the method of Arditi and incorporate the method wherein distinguishing the processing agent from other processing agents in view of the teachings of Benaron in order to ensure that the right agent is employed with the processing system.

As per **claim 29**, Arditi further discloses a method wherein the processing system apparatus comprises an analysis apparatus, the processing agent comprises an analysis agent, the analysis agent being administered to the analysis subject and detecting in response to the administering of the analysis agent\_a condition of the analysis subject as the process result (col. 4, lines 1-25; col. 7, lines 15-60).

5. **Claim 23**, is rejected under 35 U.S.C. 103(a) as being unpatentable over Arditi U.S. Patent No. 5,526,816 in view of Benaron U.S. Patent No. 5,167,297 as

applied to claim 1 above, and further in view of Brock-Fisher U.S. Patent No. 6,612,989 B1.

As per **claim 23**, both Arditi and Benaron et al failed to explicitly disclose a method, wherein the step of selectively modifying subsequent operation of the processing system comprises at least partially disabling output of the process result in the absence of the distinctive signature characteristic.

Brock-Fisher discloses disclose a method, wherein the step of selectively modifying subsequent operation of the processing system comprises at least partially disabling output of the process result in the absence of the distinctive signature characteristic (see abstract).

Accordingly it would have been obvious to one of ordinary skill in the art at time of applicant's invention to modify the method of Arditi and incorporate the method wherein the step of selectively modifying subsequent operation of the processing system comprises at least partially disabling output of the process result in the absence of the distinctive signature characteristic in view of the teachings of Brock-Fisher in order to ensure that the right agent is employed with the processing system.

6. **Claim 45** is rejected under 35 U.S.C. 103(a) as being unpatentable over Arditi U.S. Patent No. 5,526,816 in view of Benaron U.S. Patent No. 5,167,297 as applied to claim 1 above, and further in view of Green U.S. Patent No. 6,217,554 B1.

As per **claim 45**, both Arditi and Benaron failed to explicitly disclose the method wherein the processing agent substance comprises radioactive isotopes.

Green discloses the method wherein the processing agent substance comprises radioactive isotopes (col. 1, lines 50-55).

Accordingly it would have been obvious to one of ordinary skill in the art at time of applicant's invention to modify the method of Arditi and incorporate the method wherein the processing agent substance comprises radioactive isotopes in view of the teachings of Green in order to ensure that the right agent is employed with the processing system.

### **Conclusion**

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

**Examiner's Note:** Examiner has cited particular columns and line numbers in the references as applied to the claims below for the convenience of the applicant. Although the specified citations are representative of the teachings in the art and are applied to the specific limitations within the individual claim, other passages and figures may apply as well. It is respectfully requested that the applicant, in preparing the responses, fully consider the references in entirety as potentially teaching all or part of the claimed invention, as well as the context of the passage as taught by the prior art or disclosed by the examiner.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Charles C.L. Agwumezie** whose number is **(571) 272-6838**. The examiner can normally be reached on Monday – Friday 8:00 am – 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Andrew Fischer** can be reached on **(571) 272 – 6779**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business

Art Unit: 3621

Center (EBC) at 866-217-9197 (toll free). If you would like assistance from a USPTO

Customer Service Representative or access to the automated information system, call

800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Charlie C Agwumezie  
Examiner, Art Unit 362  
February 16, 2008

/ANDREW J. FISCHER/  
Supervisory Patent Examiner, Art Unit 3621